MEDI-CAL DRUG USE REVIEW BOARD
MEETING MINUTES
Tuesday, November 8, 2005
10:00 a.m. to Noon

Location: Department of Health Services
1501 Capitol Avenue, Room 71.4003
Sacramento, CA 95814

Topic	Discussion
1) CALL TO ORDER	Meeting was called to order by Dr. McBride Members present: Janeen McBride, Andrew Wong, Ross Miller, Patrick Finley, Marilyn Stebbins, Robert Mowers, Tim Albertson Members absent: Craig Jones, Stephen Stahl, Kenneth Schell, Art Whitney
2) APPROVAL OF LAST MINUTES	Dr. McBride moved to approve the minutes from the September 13, 2005, Board meeting. Dr. Miller requested a correction of the minutes to reflect "NHLBI" rather than "NAEPP" guidelines. Minutes unanimously approved as amended.
3) DISCUSSION OF ONGOING PROJECTS	A. Atypical Antipsychotic Polypharmacy Report 1. Dr. Lisa Ashton, Department of Health Services (DHS), presented this item as a follow-up of the 2004 report. Since atypicals have been the highest cost therapeutic class since 1997, the Department has looked at multiple ideas to improve utilization in areas of polypharmacy and, earlier, appropriate augmentation. This study only addresses polypharmacy, defined as concurrent use of 2 or more antipsychotics. 2. The analysis used one month of data (May 2004) as a snapshot. For this one month, costs were more than $97 million for about 318,000 claims and 4,500 individual pharmacies. The Top 10 pharmacies were providers for Long-Term Care (LTC) facilities. Three months of claim history was then extracted for these 10 pharmacies to establish polypharmacy. 3. DHS chose to target pharmacy providers rather than "prescribers" because the pharmacy provider data is more accurate in the system, and also because prior experience with targeting prescribers was not effective. 4. DHS proposed polypharmacy intervention: i. As a pilot, send a letter to the Top 10 LTC pharmacies with a list of patients that have received polypharmacy, including the combinations of drugs. If pilot is successful, expand intervention to the next 100 pharmacies. ii. Board comments/recommendations for changes to LTC draft letter: send letter to corporate owner of LTC as well, send copy to named medical director and named pharmacist consultant, add a bolded title to the letter, do not abbreviate DUR, remove statement "….please disregard the recommendation" and combine the remaining sentence with the next sentence, state (on front page) what action should be taken and how to respond to this letter, state that a follow-up audit will be performed in 3/6 months, and copy Lori DeMartini (DHS, Audits and Investigations). B. Acetaminophen (APAP) Toxicity Monitoring 1. Dr. Ashton presented this item as a follow-up to the Chronic Opioid Utilization report presented at the September Board meeting. DHS did a chronic opioid medication evaluation that was followed for one year. It appears that we are doing pretty well on long-acting and short-acting chronic opioid use. However, the Board requested DHS monitor the cumulative APAP product within the tool but not look at APAP when dispensed by

itself but when used in conjunction with other products, combination drugs such as narcotics or opioids.

2. This analysis was done using a 5-month period (April 1 through August 31, 2005) using all agents from the formulary file that have some type of APAP component, excluding cold and flu products. The cold and flu products were not used because it is too hard to add up their doses, these products are mostly liquid, and it is unknown if the patient is regularly taking the product once purchased. The goal was to identify patients who were supposedly taking or had access to greater than 4 grams of APAP per day using claim service dates and quantities.

3. The significant findings of this analysis were that 581beneficiaries received greater than 4 grams of APAP for a period of more than 100 days within the 150 day period, and of these 581 beneficiaries, 31 had a diagnosis code for liver or kidney type diseases.

4. Board recommends the following actions: send a patient letter to the 31 beneficiaries with renal/hepatic disease, write a provider bulletin, send a letter to providers (pharmacy and prescriber) of the 581 beneficiaries, implement a duration of therapy system edit whereby all APAP doses are added and there is a maximum cumulative dose of 4 grams APAP per day, otherwise Treatment Authorization Request required. The consensus of the Board is that all these items should be completed, not just one or two.

5. The Board also recommended that the DHS expand the analysis to cover a one-year period. This analysis should keep the 100 day window and identify the number of days that the beneficiary exceeded 4 grams, 8 grams, or 16 grams of APAP.

C. Several Board members are writing studies to go to the Committee for Protection of Human Subjects.

1. Dr. Albertson- Asthma Study looking at issues of National Guidelines and trying to extract whether or not these guidelines are being met in the Medi-Cal Fee-For-Service population by reviewing the prescriptions being filled, specifically, duplications, high use of short-acting inhalers and use of inhaled steroids.

2. Dr. Wong- Rheumatoid Arthritis Study is looking to expand the pilot work done in Los Angeles County. Looked at practice patterns, use of the new biologic agents versus traditional DMARDs for treatment of chronic inflammatory arthritis and rheumatoid arthritis. Allowed physicians to use best practices and identified those practices, and balanced them with the costs involved with using the medications. In Los Angeles County, most practice patterns were appropriate. There were some areas of improvement through quality improvement activities. Opportunity exists to look at the entire Medi-Cal population, realizing that over 50% of Medi-Cal population is already located in Los Angeles County. Proposal put together to be submitted to the DHS, Institutional Review Board, to look at the entire Medi-Cal population through two approaches. One, identify patients through arthritis category or, two, identify them from arthritis medications they are dispensed and then match that code to see what the patient is being treated for. Once the above is complete, subgroup patients into those taking traditional DMARDs versus those taking new biologic agents. A second part of the Study would look at the impact Medicare Part D has had on rheumatoid arthritis patients. Assuming patients are moving from an open formulary to more restrictive formularies, determine impact of change on access, quality, and patient's perception of how they are doing.

3. Dr. Finley- Antidepressants in Children Study. Dr. Finley and Dr. Stahl are concerned about some of the more controversial FDA black box warnings that have been issued in the last couple of years and the prescribing patterns and total resource utilization in morbidity/mortality of these warnings on children and adolescents. The methodology is in its infant stages. Are we seeing a decrease in prescriptions for antidepressants for children based on this black box warning? Some of the reports suggest a 25% decline for the first quarter by various PBMs around the country. This has not been sustained. Are our children being switched to fluoxetine because it is the only FDA approved drug for treatment of depression? If we are seeing a decrease in antidepressant prescriptions, is

	there a subsequent increase in psychotherapy visits or is there an increase in emergency room visits? There should be an increase in psychotherapy visits, otherwise the implication is that we are just not treating these children anymore. We will look at the morbidity and mortality data as well. It is coded when there are serious suicidal gestures and Dr. Ashton has already looked at this for an eight-month period after the warning. One question currently is what time periods to look at because 2004 was a strange year, in that it was when this issue raised its ugly head and there were warnings out of the U.K., preliminary warnings out of the FDA, and then the official black box warning in September/October 2004. Might look at a 2003 snapshot and snapshot of 2005 and see what impact we can find. There are a lot of variables that can be looked at.
4) QUARTERLY UTILIZATION REPORT	A. Quarterly Report for DUR Board review: 1. Dr. McBride noted that there are an awful number of soft alerts, which pharmacists override, and there is a need to take a more serious look at eliminating alerts that are not doing any good. After further discussion, the Board requested to receive the following information prior to the next Board meeting so further discussions may occur at the next DUR Board meeting: • The current "target drug list" since these drugs can receive virtually any alert • A list of all of the alerts with definitions, OBRA requirements, etc. • New criteria that was adopted by the DUR Board approximately one year ago to determine "target drugs" We have alerts that are happening now and we have a process this Board looked at some time ago. We have come halfway. We have a new set of alerts that have not been implemented yet the old ones are still out there, from the original list, and alerts are being generated based upon that. The original criteria was high risk, high expense, high utilization. 2. The DHS is in the process of writing the system change notice to redo the entire DUR system. Now is the time to identify what is and is not working within the current system. Determine what you want this system to do so it can be written into the requirements section. The DHS anticipates a six-month requirements gathering period. 3. Regarding Table 4A, Dr McBride requested an explanation as to why we have innovator versus GPI? Innovator is a brand name product and non-innovator is a generic. Would the percentage increase had GPI been used? Answer unknown at meeting. 4. Dr. Ashton discussed an analysis currently being done by DHS to review the top target categories. This analysis was based on findings of the "Generic Drug Usage Report" published in the Express Scripts Research Study Findings. The report and findings will be presented at the next DUR Board meeting. 5. On Table 5, drugs that required Treatment Authorization Requests (TARs), Dr. McBride requested information regarding different protocols to see which ones have the worst denial rates? Do specific drugs have a 99 or 100% approval rating for the last 20 years? Table 5 contains approved TARs where a claim has been paid. How many did we not pay because of denied TARs? Can the DUR Board make recommendations on these hard edits? Most TARs are submitted based on the six-prescription limit so this increases the TAR volume.
5) DHS COMMENTS	A. Potentially coordinating DUR and MCDAC (Medi-Cal Drug Advisory Committee) Activities 1. MCDAC and DUR overlap in their roles with respect to step-therapy and practice guidelines.

	2. MCDAC Responsibilities: • Make formulary decisions based on a document that is similar to a dossier, but provides more summary data. This "AMCP Light" would contain the following: o Off-label uses o Course in therapy o Comparator drugs o Place in national guidelines • MCDAC would then make a formulary or "policy" recommendation. 3. The DUR Board would determine if the policy change complies with standard practice guidelines and track whether the policy is being adhered to by practitioners. 4. Looking at options for both the DUR Board and MCDAC, options include combining the two groups, having meetings on same days with overlap to discuss the items in common, or at least having them on the same day so if you wish to attend the other meeting, you can.
6) EDUCATIONAL BULLETIN(S)	A. Atomoxetine/Antidepressants Bulletin 1. Dr. Leticia Melgoza, Electronic Data Systems Corporation, discussed a proposed bulletin to alert providers of the recent FDA warnings of suicidality in children/adolescents taking atomoxetine. Utilization data and age distribution of the beneficiaries using atomoxetine was also included for provider awareness. 2. DUR Board recommendations- If you want providers to read anything, it must be one page, back to front, increase font, take out detail, bold and bullet key messages. The graphs provide striking information. 3. Put effort into distribution of DUR educational bulletins other than the way it is currently going out. Think about linking up with the medical board, the pharmacy board, electronically sending it out to pharmacies. This is good information, you spend a lot of time doing it, and I do not think you get a lot out of it. If there are other ways of getting this information out, particularly electronically, do it. The process should not include providers having to actively do anything in order to obtain the information.
7) 2006 CALENDAR	A. Options for possible meeting dates 1. DUR Board Meetings (Tuesday) i. February 14th ii. May 9th iii. September 12th iv. November meeting date still in discussion 2. MCDAC Meetings (Thursday) i. February 2nd ii. May 4th iii. August 10th iv. November meeting date still in discussion B. Board unanimously voted to attempt to have the meetings on the same date with a lunch break in between. Other option may be to overlap the date of some, but not all, of the meetings.

8) PUBLIC AND DUR BOARD COMMENTS	A. Board Comments- Dr. Wong inquired about exchange of claims information with Medicare Prescription Drug Plans (PDPs) after implementation of Medicare D. DHS stated that there will be 8 PDP's serving the most of the dual Medicare/Medi-Cal beneficiaries, each having approximately 122,000 beneficiaries/members. DHS will provide history claims files for the prior 4 months, and is hoping to have an ongoing exchange of data with PDPs and possibly monitor patients for medication therapy management. CMS has developed a committee for the exchange of data efforts. B. Public Comments- No public comments received.
9) PUBLIC OR DUR	None
10) DATE OF NEXT DUR BOARD MEETING	Tentatively scheduled for February 14, 2006.
11) ADJOURNMENT	The meeting adjourned at 11:50 PM

Summary of Action Items:

1. **Amend 9/13/05 meeting minutes as requested.**

2. **Atypical Antipsychotic Polypharmacy Report**
   a) Amend LTC draft letter as follows: send letter to corporate owner of LTC as well, send copy to named medical director and named pharmacist consultant, add bolded title, do not abbreviate DUR, remove statement "…please disregard the recommendation" and combine the remaining sentence with the next sentence, state (on front page) what action should be taken and how to respond to this letter, state that a follow-up audit will be performed in 3/6 months, and copy Lori DeMartini (DHS, Audits and Investigations).

3. **APAP Toxicity Monitoring Report**
   a) Expand analysis to cover a one-year period, keeping 100 day window, identifying number of days exceeding 4 grams, 8 grams, and 16 grams of APAP.

   b) Board recommendations: send patient letter to those beneficiaries with renal/hepatic disease, write a provider bulletin, send a letter to providers (pharmacy and prescriber) of the beneficiaries receiving high doses for more than 100 days, implement a duration of therapy system edit with maximum 4grams APAP per day (cumulative dose, all drugs), otherwise Treatment Authorization Request needed. Maureen Tooker to investigate system requirements for this system edit.

4. **Quarterly Utilization Report**
   a) Board to receive the following information prior to the next Board Meeting so they can review before the next Board meeting.
      1. The current "target drug list"
      2. A list of all of the alerts with definitions, OBRA requirements, etc.
      3. New criteria adopted by the DUR Board approximately one year ago by DUR Board to determine "target drug"

   b) Board to identify any system changes they want to see in the DUR system.

   c) On Table 4A, are their differences when reporting innovator versus GPI?

   d) Dr. Ashton to present report and findings on generic utilization in the Medi-Cal population based on the Express Scripts Study.

   e) Do specific TAR drugs have a 99 or 100% approval rate? Does the DUR Board have authority to request hard edit changes to the TAR system?

5. **Educational Article**
   a) Prior to publication, condense the atomoxetine/antidepressant article to 1 page of text while keeping the graphs.

b) Look at distribution of educational articles and determine if there are other ways, particularly electronically, to push out this information. The process should not include providers having to actively do anything to obtain the information.

6. 2006 Calendar

a) Finalize 2006 calendar.